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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,310	12/12/2003	Holger Kartheus	104035.272556	2222

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 02/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/735,310	KARTHEUS ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-41 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-41 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 12/12/03.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' preliminary amendment filed 07/27/2004; IDS filed 12/12/2003.

Under rule 1.126, claims 28-40 presented in the preliminary amendment filed on 07/27/2004 have been renumbered as claims 28-41 consecutively.

Claims 1-41 are pending and included in the prosecution.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-7, 12, 19-22, 26-28, 33, 34, 37, and 38 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, and 5-12 of copending Application No. 10/700,932 ('932) in view of US 5,844, 013 ('013). The referenced copending application and the instant application are claiming common subject matter directed to polyurethane matrix comprising active agent and penetration enhancer in the same amounts and the polyurethane matrix having the same thickness. The difference between the present claims and the copending claims in the reference application is that the present claims are directed to polyurethane matrix in the form of gel while the copending claims are generic regarding the formulation of the matrix. US '013 teaches polyurethane gel foam used in medicine and as a wound dressing because it has self adhesive properties on the skin and can be pulled off painlessly from normal skin (abstract; col.18, lines 14-17). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver a polyurethane adhesive matrix comprising active agent and enhancer as claimed in the copending application '932, and use the gel form of the polyurethane matrix as disclosed by US '013, motivated by the teaching of US '013 that the polyurethane gel matrix can be pulled off painlessly from the skin, with reasonable expectation of having a polyurethane gel matrix comprising active agent and permeation enhancer that delivers active agents and causes no pain or discomfort during use and upon removal from the skin of the user.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 23 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 23 recites the limitation: "backing material does not cover at least portion of the periphery of the polyurethane gel matrix". Recourse to the specification and figures, nowhere applicants have disclosed this limitation. On page 22, lines 4-6, page 25, lines 19-24, and page 26, lines 4-9, 26-31, as well as the figures, applicants disclose that the periphery of the backing or the periphery of the adhesive covering the backing is not covered by the polyurethane matrix, and not *vise versa* as claimed. Therefore, the preliminary amendment has introduced a new matter.

For examination purpose and based on applicant's disclosure, claim 23 will be interpreted as "the periphery of the backing material, at least in the part, is not covered by the polyurethane matrix".

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 5, 23 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 5 and 35, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. In the present instance, the broad limitation is "pharmaceutically active substances" and the narrow limitations are "essential oils", and "antiseptics".

Furthermore, the expression "cosmetic skin-care additives" in claims 5 and 35 does not set forth the metes and bounds of the claim. Recourse to the specification does not define the expression.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-17, 19-23, 25-36, 38, 39, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2005/0048104 ('104).

US '104 teaches transdermal drug delivery device comprising a backing layer and a reservoir of polyurethane matrix material comprising from 1-20% active agent and from 2-20% permeation enhancer (abstract; paragraphs 0045, 0054, 0064). The reference teaches that by manipulating the ratio of hard and soft segments of the polyurethane, a range of permeability for a given drug can be obtained; and by changing the nature of the soft segment, polyurethanes having different hydrophobic/hydrophilic character or drug solubility can be obtained in order to accommodate different drugs (paragraphs 0033, 0061, 0062). The thickness of the matrix reservoir is from 1-12 mil, i.e. 25μm-300μm (paragraph 0057). Examples of permeation enhancers include C_{10}- C_{20} fatty acid esters including isopropyl myristate (paragraph 0051). The active agent includes vasodilators, i.e. hyperemic drugs

(paragraph 0054). The backing material is preferably occlusive and made of polyethylene or polyester (paragraph 0052). Figure 2 shows that the periphery of the backing is not covered by the polyurethane matrix.

US '104 does not expressly teach the polyurethane matrix to be a gel as claimed in claims 1 and 26, or the foamed polyurethanes as claimed in claims 4 and 34. The reference, however, teaches that by manipulating the ratio of hard and soft segments of the polyurethane, a range of permeability for a given drug can be obtained; and by changing the nature of the soft segment, polyurethanes having different hydrophobic/hydrophilic character or drug solubility can be obtained in order to accommodate different drugs, and these teachings would have motivated one having ordinary skill in the art at the time of the invention to manipulate the polyurethane ingredients to obtain gel or foam according to the nature of the active agent to be delivered, with reasonable expectation of having transdermal patch comprising gel polyurethane matrix, that can be foamed, to obtain the optimum permeability and solubility of the specific active agents to be delivered to the skin of the user.

The reference does not teach the adhesive between the backing and the polyurethane matrix, as claimed in claim 9, however, laminating different layers of a transdermal patch using adhesive is a well known method in the transdermal art and does not impart patentability to the claims, absent evidence to the contrary.

10. Claims 1-17, 19-23, 25-36, 38, 39, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2005/0048104 ('104) combined with US 4,404,296 ('296).

US '104 teaches transdermal drug delivery device comprising a backing layer and a reservoir of polyurethane matrix material comprising from 1-20% active agent and from 2-20% permeation enhancer (abstract; paragraphs 0045, 0054, 0064). The reference teaches that by manipulating the ratio of hard and soft segments of the polyurethane, a range of permeability for a given drug can be obtained; and by changing the nature of the soft segment, polyurethanes having different hydrophobic/hydrophilic character or drug solubility can be obtained in order to accommodate different drugs (paragraphs 0033, 0061, 0062). The thickness of the matrix reservoir is from 1-12 mil, which is 25μm-300μm (paragraph 0057). Examples of permeation enhancers include C_{10}- C_{20} fatty acid esters including isopropyl myristate (paragraph 0051). The active agent includes vasodilators, i.e. hyperemic drugs (paragraph 0054). The backing material is preferably occlusive and made of polyethylene or polyester (paragraph 0052). Figure 2 shows that the periphery of the backing is not covered by the polyurethane matrix.

US '104 does not expressly teach the polyurethane matrix to be a gel as claimed in claims 1 and 26, or the foamed polyurethanes as claimed in claims 4 and 34.

US '104 does not teach the adhesive between the backing and the polyurethane matrix, as claimed in claim 9, however, laminating different layers of a transdermal

patch using adhesive is a well known method in the transdermal art and does not impart patentability to the claims, absent evidence to the contrary.

US '296 polyurethane gel matrix that can be coated on a substrate and used to deliver pharmaceuticals to the skin including anti-rheumatic agents (abstract; col.2, lines 28-31; col.10, lines 31-51; col.13, 50-55; col.15, lines 20-30). The polyurethane gel can be foamed (col.13, lines 57-58). The polyurethane gel matrix uniformly releases the active agent to the surrounding environment even solid and difficultly volatile agents and is exceptionally stable (col.2, lines 33-36; col.5, line 33; col.15, lines 39-42).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal patch comprising a polyurethane matrix as taught by US '104, and replace the polyurethane matrix by the gel matrix form disclosed by US '296, motivated by the teaching of US '104 that by manipulating the ratio of hard and soft segments of the polyurethane, a range of permeability for a given drug can be obtained; and by changing the nature of the soft segment, polyurethanes having different hydrophobic/hydrophilic character or drug solubility can be obtained in order to accommodate different drugs, and further motivated by the teaching of US '296 that polyurethane gel matrix uniformly release the active agent to the surrounding environment even solid and difficultly volatile agents and is exceptionally stable, with reasonable expectation of having a transdermal patch comprising polyurethane gel matrix that is exceptionally stable and delivers active agents, even difficultly volatile agents, uniformly to the skin.

11. Claims 18, 24, 37 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '104 by itself or combined with US '296 as discussed above, and further in view of US 5,306,503 ('503).

The teachings of US '104 and US '296 are discussed above. The combined teachings of the references do not teach the specific active agent claimed in claims 18, 24, 37 and 40. However, US '104 teaches hyperemic drugs, and US '296 teaches anti-rheumatic agents.

US '503 teaches transdermal drug delivery device for topical and systemic administration of active agents through the skin and useful for treating rheumatic diseases by delivering agents that locally stimulate the blood flow and create a local feeling of warmth, such as capsaicin, benzyl nicotinate, and nonivamide (col.3, lines 35-37; col.5, lines 15-25).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal patch comprising a polyurethane gel matrix as taught by US '104 be itself or combined with US '296, and add to (or replace by) the vasodilator disclosed by US '104 or the anti-rheumatic agent disclosed by US '296 any of capsaicin, benzyl nicotinate, or nonivamide as disclosed by US '503, motivated by the teaching of US '503 that these agents locally stimulate the blood flow and create a local feeling of warmth and useful for treating rheumatic diseases, with reasonable expectation of having transdermal device comprising polyurethane gel matrix comprises capsaicin, benzyl nicotinate, or nonivamide that locally stimulate the blood flow and create warmth to the skin of the user in need of such treatment.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

IG

Isis Ghali

ISIS GHALI
PATENT EXAMINER